| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 51D0234577 | 01/03/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| War Memorial Hospital Inc | 1 Healthy Way, Berkeley Springs, WV | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the Laboratory Manager (LM), the laboratory failed to test arterial blood gas proficiency samples with the patient workload using the respiratory therapists who routinely perform testing for 6 of 6 PT events in 2016 and 2017. The findings include: 1. Review of the laboratory's PT records identified the lack of testing of arterial blood gas PT samples by 6 of 6 respiratory therapists for 6 of 6 PT events in 2016 and 2017. 2. On 1/3/18 at approximately 10:00 AM, the LM stated the respiratory therapists did not perform PT testing in 2016 and 2017. |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's American Proficiency Institute proficiency testing records, and interview with the Laboratory Manager (LM), the Laboratory Director failed to sign the vendor's proficiency testing attestation statement for 5 of 6 proficiency testing events participated in from 2016-2017. The findings include: 1. |

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| | Review of the laboratory's proficiency testing records revealed the testing personnel did not sign the vendor's proficiency attestation statement for the 2016 Immunology /Immunohematology-1st, 2nd and 3rd Event. 2. Review of the laboratory's proficiency testing records revealed the testing personnel did not sign the vendor's proficiency attestation statement for the 2017 Immunology/Immunohematology-1st, and 2nd Event. 3. On 1/3/18 at approximately 9:45 AM, the LM confirmed the findings. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy and procedure manual, Sysmex CA 560 records and interview with the Laboratory Manager (LM), the laboratory failed to follow their policy and verify the accuracy of the INR calculation for 2 of 2 years reviewed. Record review was for 2016 and 2017. The findings include: 1. Review of the laboratory's policy and procedure manual identified a policy, "Annual Establishment of Reference and Therapeutic Ranges and INR Calculation Checks", which states "With every lot change of reagent or annually, the following are performed: PT and APTT reference ranges are established; INR calculations on patient reports are checked to verify that they are correct; APTT-based heparin therapeutic range is validated." 2. Review of the laboratory's Sysmex CA 560 records identified no documentation of the "INR" calculation being verified for patient reports for the years of 2016 and 2017. 3. On 1/3/18 at approximately 11:30 AM, the LM confirmed the findings. |
| **D5555** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(c)(f)<br><br>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy and procedure manual, Blood Bank alarm check records, and interview with the General Supervisor #1 (GS1), the laboratory failed to document the temperature for 3 of 4 Blood Bank refrigerator quarterly alarm tests performed in 2017. The findings include: 1. Review of the laboratory's policy and procedure manual identified a policy, "Blood Bank Refrigerator", that states "3. FUNCTION VERIFICATION; D. Test Temperature Alarm System and Record-Testing of the temperature alarm system should be performed and recorded at least quarterly by Biomedical Department." 2. Review of the Blood Bank alarm check |

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| | records identified no documentation of the temperature of quarterly alarm test for 3 of 4 tests performed in 2017. 3. On 1/3/18 at approximately 2:00 PM, GS1 confirmed the findings. |